



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/765,064	03/25/97	CZMIELEWSKI	

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EXAMINER
MACHILL

ART UNIT PAPER NUMBER
1.035

DATE MAILED: 06/03/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/765,064	Applicant(s) Czrnielewski et al
	Examiner Keith MacMillan	Group Art Unit 1205

☒ Responsive to communication(s) filed on Jan 6, 1997

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-29 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-29 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claim Rejections - 35 U.S.C. § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 10 is rejected under 35 U.S.C. 102(b) as being clearly anticipated by Borgman, Chemical Abstracts AN 1989:502704 (corresponding to WO 8806888.) A copy of the abstract is provided as evidence of the disclosure. Borgman teaches topical formulations of metronidazole for the treatment of skin disorders. As the disclosure meets every critical limitation of the claim, the claim is anticipated.

3. Claims 10-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Busch et al, Chemical Abstracts AN 1976:145357. Busch et al teach compositions containing both clindamycin (registry number 18323-44-9) and metronidazole (registry number 443-48-1.) Synergism resulting from the combination is also disclosed. Pharmaceutically acceptable carriers for the composition are also disclosed. Thus, the disclosure meets every critical limitation of these claims.

The recitations of intended use, and to "topical" compositions, in the claims are noted. However, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the

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claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. *In re Casey*, 152 USPQ 235 (CCPA 1967); *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Claim Objections

4. Claims 12-14, 16-17, 21-22, and 25 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. These claims differ from their respective dependent claims only by recitations of intended use. As they do not contain limitations which result in structural differences in the composition, they do not further limit the claims from which they depend.

Claim Rejections - 35 U.S.C. § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 10-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayer et al, US Patent 4,018,918, in view of Borgman (WO 8806888, published 1988).

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Ayer et al teach topical compositions which contain both clindamycin and an antiinflammatory steroid. The compositions are useful to treat a variety of skin disorders, including acne. See the abstract, which is provided as evidence of the disclosure. The claims differ in the type of antiinflammatory agent which is to be present in the composition. Ayer et al teaches a steroidal antiinflammatory; Applicants' claims call for metronidazole as the antiinflammatory. Borgman teaches that metronidazole is an excellent topical antiinflammatory, suitable for use in topical treatments of skin disorders such as acne. It would have been obvious to one of ordinary skill in the art to formulate a topical composition according to the instant claims, by substituting metronidazole rather than the steroid as the antiinflammatory. One would have been motivated to make the substitution because this prior art combination established metronidazole and the steroid shown are art equivalents. Further motivation to make the substitution comes from the very well known synergism seen in treating microbials, especially *bacteriodes fragilis*, when clindamycin and metronidazole are combined. See for example Busch et al, Chemical Abstracts AN 1976:145357. Still more motivation to combine these two ingredients in a topical solution comes from Deckner et al, Chemical Abstracts AN 1993:503333, published 1993. (Deckner et al corresponds to WO 9307903. A copy of the abstract is provided as evidence of this disclosure as well.) Deckner et al teach topical compositions which optionally contain both clindamycin as an antimicrobial and metronidazole as and antiinflammatory. In view of the foregoing, the claimed topical composition is rendered obvious by this combination of prior

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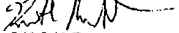
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art. Claims 26-29 are included in this rejection because the topical route of administration and treatment of skin disorders is clear from the combination of references for the same reasons.

7. Any inquiry concerning this communication should be directed to Keith MacMillan at telephone number (703) 308-4614.

Keith MacMillan


5/28/97